

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Eberhard Nieschlag et al.

Serial No.: 09/764,149

Group Art Unit: 1615

Filed: January 19, 2001

Examiner:
Rachel M. Bennett

For: MALE CONTRACEPTIVE FORMULATION COMPRISING NORETHISTERONE

SUPPLEMENTAL AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

Supplemental to the Amendment filed May 21, 2002, kindly amend the above-identified application as follows.

IN THE SPECIFICATION

Replace page 20, in its entirety, with the attached new page 20. A marked up version is not supplied since no changes are made to the page, it is merely being replaced by a more legible copy.

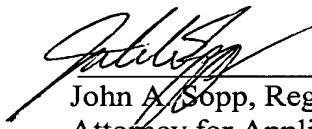
#1110
YC
6-6-02
RECEIVED
TECH CENTER 1600/2900
MAY 29 2002

REMARKS

A substitute, more legible, page 20 is being submitted per the Examiner's request in the Office Action of December 21, 2002.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



John A. Sopp, Reg. No. 33,103
Attorney for Applicants
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Boulevard, Suite 1400
Arlington, VA 22201
Direct Dial: 703-812-5315
Facsimile: 703-243-6410
Email: sopp@mwzb.com

FILED: May 28, 2002

1.1.1 Study flow chart

Visit	Screening	Treatment												Observation			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Assessment		A	B ¹	day 0 ²	W2 ³	W4	W6	W8	W12	W16	W18	W20	W24	W28	W35	W44	W56
Group A																	
NET-Et administration (mg)				200				200		200		200					
TU administration (mg)					1000			1000		1000		1000					
Group B																	
NET-Et administration (mg)				400				400		400		400					
TU administration (mg)					1000			1000		1000		1000					
Group C																	
NET-A administration (mg)																	
Dispensation of vials																	
TU administration (mg)				10 mg				daily									
Informed Consent/Demographics	ABC				V12				V34								
Check of Inclusion/Exclusion	ABC																
Randomization/Diary dispensed	ABC																
Medical/androl/medication history	ABC	ABC	ABC														
Vital signs	ABC	ABC	ABC														
Physical examination	ABC																
Andrological examination	ABC																
Semen analysis	ABC	ABC															
General laboratory	ABC																
Hormones	ABC	ABC															
Exam/Ultrasoundography of prostate		ABC															
Ultrasoundography of testes		ABC															
Return of diary/vials, if available																	
AEs/concomitant medication																	
Questionnaire	ABC	ABC															

Table 1

¹ At least 7 days after visit 1² Not more than 8 weeks after visit 1³ A deviation of ± 5 days will be tolerated